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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/540,999	06/28/2005	Hesham Morsi	Morsi-01	9037

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EXAMINER

GANESAN, SUBA

ART UNIT	PAPER NUMBER
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3738

MAIL DATE	DELIVERY MODE
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07/27/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/540,999	MORSI, HESHAM	
	Examiner	Art Unit	
	Suba Ganesan	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 June 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-57 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-57 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 June 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>6/28/2005</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Objections

1. Claim 4 is objected to because of the following informalities: The term "non-linear longitudinal axis" is unclear since convention dictates that an axis is linear. Appropriate correction is required.
2. Claim 8 is objected to because of the following informalities: TFE, PTFE and ePTFE should be referred to by their generic names instead of by acronym, i.e., tetrafluoroethylene, etc. Appropriate correction is required.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-4, 6, 8-10, 16-19, 22-27, 31-33, 38, 42, 45-49, 54-57 are rejected under 35 U.S.C. 102(b) as being anticipated by Rogers et al. (U.S. Pat. No. 5,607,468).
5. Rogers discloses an inflatable tubular graft with a first outer wall 80 and a second inner wall 70 with at least one fused juncture creating fluid impermeable seals and fluid communicating passages (see fig. 11 for example) and a valve to inflate the graft (col. 2 lines 54-60). Rogers graft includes a circumferential plurality of junctures where a passage 32 conveys fluid within the interstitial space (see fig. 1). Catheter 44 locates

and inflates the tubular graft. With respect to claim 4, as best understood, a fused juncture defines a non-linear longitudinal length of the graft (see fig. 7). The inner and outer walls are comprised of materials having different elasticity (col. 1 lines 25-34), specifically PTFE (col. 2 lines 63-64). A fluid fills the interstitial space (col. 2 lines 54-60). The graft has a first and second end with different diameters (see fig. 7). With respect to claims 17-18, the intended use of the device carries no patentable weight in the absence of distinguishing structure; the device of Rogers is fully capable of treating aneurisms and atherosclerosis (col. 1 lines 20-23). The outer wall of the Rogers graft forms a corrugated surface while the inner wall is smooth (fig. 11). A method is disclosed of using a catheter **44** to deliver and inflate the graft (col. 3 lines 24-39). The graft reinforces the blood vessel wall (fig. 6). The inflated graft can be used with a diseased vessel wall (col. 1 lines 21-23), which inherently isolates the diseased vessel wall from the lumen.

6. With respect to claim 33 and 38, Rogers discloses inserting a two walled graft using a catheter, the two walled graft having a fluid seal at each end (note that fluid cannot permeate outside the graft wall on either end, which is what examiner is considering to be a fluid seal at each end), a plurality of connectors radially oriented (note that examiner is considering the fused portions of the first and second walls to be 'connectors', and the fact that they are arranged around the circumference of the graft to be 'oriented in a substantially radial direction), and a valve to regulate inflation fluid (fig. 1, col. 3 lines 24-40). With respect to claim 45-47 the graft is of a pre-selected inflatable dimension and shape (fig. 2) and can have varying length connectors (fig. 7).

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims **7,34-37,39-41** and **43-44** are rejected under 35 U.S.C. 102(b) as anticipated by Rogers et al. (U.S. Pat. No. 5,607,468) or, in the alternative, under 35 U.S.C. 103(a) as obvious over Rogers et al. (U.S. Pat. No. 5,607,468) in view of Lazim (U.S. Pat. No. 5330528).

9. Rogers is explained supra, including a graft made of PTFE or ePTFE (col. 2 line 61-col. 3 line 3), which is a material used in applicants invention. Since Rogers has the specific material disclosed, it is inherent that the graft of Rogers will include non-elastic material. In the alternative, Rogers is silent as to the elastic properties of the inflatable graft. Lazim teaches the use of flexible but inelastic materials in inflatable grafts for the purpose of controlling the contour and size of the graft (col. 6 lines 22-27). Therefore it would have been obvious to one of ordinary skill in the art to combine the teaching of non-elastic materials from Lazim with the graft of Rogers for the purpose of creating a graft with a pre-determined shape and contour.

10. Claims **11-15** and **28-30** are rejected under 35 U.S.C. 103(a) as being unpatentable over Rogers et al. (U.S. Pat. No. 5,607,468) in view of Guiset (U.S. Pat. No. 4183102).

11. Rogers is explained supra. Rogers appears to lack web reinforcements within the inflatable chambers that are inelastic. Guiset teaches the use of non-elastic web reinforcements 47, 49 (see fig. 8-9, and col. 6 lines 39-65). Therefore it would have been obvious to one of ordinary skill in the art to include non-elastic web reinforcements as taught by Guiset with the graft of Rogers, the motivation to combine being: creating a support network for the inflatable chambers that further defines flexibility of the graft.

12. Claims **20-21** and **51-52** are rejected under 35 U.S.C. 103(a) as being unpatentable over Rogers et al. (U.S. Pat. No. 5,607,468) in view of Samson (U.S. Pat. No. 5370691).

13. Rogers is explained supra. However, Rogers is silent as to the inflation media used to expand the graft. Samson teaches the use of HEMA, a curable monomer, to inflate a vascular support (col. 5 lines 15-31). Therefore it would have been obvious to one of ordinary skill in the art to use a curable monomer as taught by Samson for the purpose of expanding the graft and creating a firm vascular support.

14. Claim **53** is rejected under 35 U.S.C. 103(a) as being unpatentable over Rogers et al. (U.S. Pat. No. 5,607,468) in view of Samson (U.S. Pat. No. 5370691), further in view of Chobotov et al (U.S. P.G. Pub. No.: 2003/0120338).

15. The combination of Rogers and Samson is explained supra. However, the combination lacks the use of Saline. Chobotov teaches the use of saline with polymer compounds for inflating a graft (para 20). Therefore it would have been obvious to one of ordinary skill in the art to include saline with the inflation medium to increase fluid volume without interfering with the chemical properties of the inflation polymers.

16. Claims **5** and **50** are rejected under 35 U.S.C. 103(a) as being unpatentable over Rogers et al. (U.S. Pat. No. 5,607,468).

17. Rogers is explained supra. However, Rogers lacks an outer wall with increased *longitudinal* length between each fused joint than the inner wall. However, this relationship could be easily achieved by creating circumferential inflation chambers, which is simply a 90 degree rotation of the longitudinal chambers of Rogers. This adjustment of inflation chambers is well within the knowledge of one of ordinary skill in the art, and one would be motivated to change the orientation of the inflatable chambers since such a change would be an obvious design choice that would be within the scope of the functionality of the inflatable graft.

18. Rogers further lacks disclosure of the outer wall dimension after inflation. However, a diameter of less than 10mm would be obvious to one of ordinary skill in the art since the object of the vascular graft is to support a vascular lumen. Therefore dimensions of the vascular graft mirror dimensions of the vasculature in which the graft is designed to be used, which encompasses an outer wall dimension of less than 10mm.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suba Ganesan whose telephone number is 571-272-3243. The examiner can normally be reached on M-F 8-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 571-272-4754. The fax phone

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number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/SDG/ 7/20/2007

BRIAN E. PELLEGRINO
PRIMARY EXAMINER

